

## REMARKS

### **Status of the Claims:**

Claims 1-5 were originally submitted. Claims 1-5 were rejected. Claim 1 has been amended. Amended independent claim 1 and originally submitted dependent claims 2-5 are currently pending and at issue.

Reconsideration is hereby respectfully requested in light of the following remarks.

### **Rejection Under 35 U.S.C. §112**

Claims 1-4 have been rejected under 35 U.S.C. §112, as failing to comply with the written description requirement. Claim 1 has been amended to correct a typographical error and to comply with the originally filed specification. Claims 2, 3, and 4 are dependent on claim 1, and the limitations of newly amended claim 1 are incorporated into these claims. Support for the amendment may be found at page 2, line 23 of the originally filed application.

Applicant respectfully requests that this rejection be withdrawn.

### **Rejection Under 35U.S.C. §103**

Claims 1-5 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,696,105. The '105 patent discloses a topical cream comprising (a) 0.01 to 0.25 percent Mometasone Furoate (b) 5 to 20 percent hexylene glycol (c) 1.0 to 5 percent water (d) 2.0 to 10.0 percent white wax (e) 4 to 12 percent of a lipophilic emulsifier having a HLB below 5 (f) 0.7 to 4 percent of a hydrophilic emulsifier having a HLB above 11 (g) 0.2 to 2.0 percent Titanium dioxide (h) 5 to 20 percent aluminum starch octenylsuccinate (i) 40 to 70 percent white petrolatum (j) sufficient acid to adjust the pH of the water to pH 2.5 to ±0.2. The '105 patent does not teach the viscosity or propylene glycol. The Examiner contends that it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate propylene glycol for hexylene glycol and to adjust for viscosity in the mometasone topical composition.

The use of propylene glycol in a mometasone fluorate topical cream would not have been obvious to one of ordinary skill in the art at the time of the invention for the

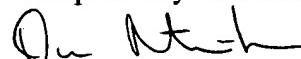
following reasons. The '105 patent claims a method of using a known mometasone cream composition to treat fungal infections, it does not claim the actual composition. The mometasone cream formulation disclosed, but not claimed, in the '105 patent is the same composition of mometasone cream claimed in U.S. Patent No. 4,808,610 (the '610 patent). The '610 patent is identified in the Background of the Invention of the currently pending patent application. The '610 patent specifically teaches away from using propylene glycol in a cream formulation of mometasone. The '610 patent describes the poor solubility and efficacy of oleaginous topical creams that have mometasone fluorate dissolved into propylene glycol. Additionally, the '610 patent teaches that mometasone fluorate/propylene glycol formulations are known to be skin irritating (the '610 patent column 1, lines 20 to 30). Surprisingly, we have developed a stable, effective, non-irritating, oleaginous, occlusive cream of mometasone in propylene glycol, despite the teaching of the prior art.

### Conclusion

In view of the foregoing remarks and amendments, Applicant respectfully submits that the grounds of rejections stated against the claims under 35 U.S.C 112 and 103 have been overcome and the claims are now in condition for allowance. Favorable action is earnestly solicited.

If the Examiner has any questions concerning the application, he is requested to call the Applicants' agent at 914-345-9001, ext. 6365.

Respectfully submitted,



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